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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/582,342	09/18/00	BRANDS	R 01975.0025

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EXAMINER	
LI,B	
ART UNIT	**PAPER NUMBER**
1648	9

DATE MAILED: 08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

PTO-90C (Rev. 2/95)

*U.S. GPO: 2000-473-000/44602

1- File Copy

Offic Action Summary	Application No.	Applicant(s)	
	09/582,342	BRANDS, RUDI	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1,2 and 7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Abstract has been entered.

Claim 10 has been amended.

Response to Amendment

This is a response to the amendment, paper No. 8, filed 06/23/01. Claim 10 is amended. Claims 1-2 and 7-25 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed.

Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claim 1 is rejection for failing to particular point out the metes and bonds of "biologicals" and recited a relative word of a desired cell volume in the claim under 35 U.S.C. 112, second paragraph, on the same grounds as previously stated in the Office Action mailed 02/12/2001. Applicant asserted that the explanation of desired volume are exemplified in the specification, One skilled in the art would not need any more information to select and achieve a specific desired cell volume. The argument is respectfully considered, but it is found unpersuasive because the disclosure of specification can not read into the claim. The claim should point out at least range the cell volume that is intended in the said claim.

Claim Rejections - 35 USC § 102

Claims 1-2 and 9-22 are rejected under 35 U.S.C. 102 (b) over the prior art of Griffiths,s document, on the same grounds as previously stated in the Office Action mailed 02/12/2001.

Applicant argues that although Griffiths teaches a general characterization of the claimed invention, the instant application provides a novel improvement over the methods taught by Griffiths, in fact Griffiths teaches away from the rapid, large, scale production of multiple generation of experimental cells of the claimed invention, e.g. the claimed inventive process as a discontinuous aspect of the scale-up approach, such as the experimentation or biological production at every cycle of the process and alleviated the problem of the long time period needed to prepare the cells and the risks of leaving them in a culture system for long amount time found in the methods as well as the cells that can be frozen for late use. The Applicant's argument is respectfully considered, however, it is not found persuasive because (1) the claimed

invention does not teaches how significant larger scale or fast speed of the instant application different from the Griffiths's teaching, (2) Griffithis does teaches all principle and every general step of scale-up culture both suspension and anchorage-dependent cells culture with every kind of cell culture carrier system disclosed in the instant application, e.g. which allow volumetric scale up to 10,000 L for batch suspension cell culture at density of 1-5x 10^6/ml or 1000 liter for batch microcarrier cultures at the density 1-5 x 10^6/ml in about 3-4 days short period, some even up to 1-3 x 10^7/ml by means of special perfusion devices , such as the spin filter (see entire document, especially page 74, lines 4-8, page 63, lines 19-21 and page 60, lines 11-13). The disclosed 3-4 days of such large scale cell culture up to 1000 liter for each cycle is recognized as a fast, large scale-up cell culture in the industry for producing many biological molecules, such as vaccine, interferon, and monoclonal antibody production etc. in the art (page 59, line 20). Therefore, the rejection is till proper and made final.

New ground of rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 7-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (Scale-up of suspension and Anchorage-dependent Animal cells in Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, pp.59-75), and Pollard (Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, Step 14-20 on page 3 and Section 3.2 on page 4-5).

Present invention is drawn to a general method for a scale-up preparation of an anchorage-dependentcells grown in a hollow fiber or cytodex-3 micro-carrier in suspension at the parking temperature 17-32more preferable at 37 °C, wherein the cells used for production diverse biological molecules, such as recombinant vaccine, protein, enzyme.

Griffiths et al. teaches all principle and every general step of scale-up culture both suspension and anchorage-dependent cells culture with every kind of cell culture carrier system disclosed in the instant application, such as hollow-fiber or anchorage dependent cell culture to a large scale, e.g. volumetric scale up to 10,000 L for batch suspension cell culture at density of 1-5x 10^6 /ml or 1000 liter for batch microcarrier cultures at the density 1-5 x 10^6 /ml in about 3-4 days short period, some even up to 1-3 x 10^7 /ml by means of special perfusion devices , such as the spin filter (see entire document, especially page 74, lines 4-8, page 63, lines 19-21 and page 60, lines 11-13). The disclosed 3-4 days of such large scale cell culture up to 1000 liter for each cycle is recognized as a fast, large scale-up cell culture in the industry for producing many biological molecules, such as vaccine, interferon, and monoclonal antibody production etc. in the art (page 59, line 20). Or alternatively, claims 1-2, 7-25 is rejected by USC 103 (a). Although Griffithis does not mention that the cells can be frozen or cell by the routine method in the art and temperature of culturing cells is at about 32-35, preferably at 37°C, the frozen cells and culturing cells is such a general, routine step and common knowledge in the art inherently associated with any or all kind of cell culture procedure as told by Pollard (see detail in entire document). Otherwise, where are the seed of every initial cell culture to start with? It is also a true that almost all cell culture system is set up at the range 27-37 °C range (27-28 ° is routinely set up for insect cell culture and 37 °C for mammal culture unless for the cells is specifically indicated that the cells is genetically engineered as a temperature sensitive expression cell lines, such as EGF receptor temperature sensitive expression cell line A391 or SRO kinase transformed 3T3 cells). The claimed invention drawn to a repeated discontinuous process is just a design choice based on Griffiths teaching with no patenable weight over the prior art or established common knowledge of cell culture protocol in the art. Therefore, the rejection is till proper and made final.

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:30 Am to 5:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 13, 2001

James C. Housel
JAMES HOUSEL 7/30/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600